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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/998,623	10/31/2001	Ahmed S. Mehanna	M0966/7001	5765

7590

09/29/2003

Helen C. Lockhart
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EXAMINER

JONES, DWAYNE C

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 09/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding:

Office Action Summary

Applicati n No.

09/998,623

Applicant(s)

MEHANNA ET AL.

Examiner

Dwayne C Jones

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-37, 39-51, 53, and 54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21,22,27-35,37,39-45,50,53 and 54 is/are rejected.
- 7) ☒ Claim(s) 23-26,36,46-49 and 51 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Claims 21-37, 39-51, 53, and 54 are pending.
2. Claims 21, 22, 27-35, 37, 39-45, 50, 53, and 54 are rejected.

Response to Arguments

3. Applicant's arguments with respect to claims 21-37-39-51, and 53, and 54 have been considered but are moot in view of the new ground(s) of rejection.

Claim Objections

4. Claims 23-26, 36, 46-49, and 51 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 27-35, 37, 39-43, 50, 53, and 54 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time

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the application was filed, had possession of the claimed invention. The claims are drawn to "a method of treating a subject having the disorder associated with calcium channel activity" by administering a compound of the general structural formula, as depicted in claim 27. The claimed methods of treatment fail to meet the requirement for an adequate written description of the claimed invention as required by 35 U.S.C. 112, first paragraph. There is insufficient descriptive support for the generic limitation "a method of treating a subject having the disorder associated with calcium channel activity." Furthermore, the claimed methods require treatment of an unspecified disease and no evidence indicates that a treatable disease, other than the treatment of hypertension, (as depicted in Figures 2-6 of the instant specification) was known to Applicant. In addition, applicants have only adequately described the five (5) compounds that are encompassed by the family of compounds of the invention, as listed in Figures 2-6. Moreover, applicants have only adequately described the combined use of the antihypertensive agent of Diltiazem in order to show the antihypertensive properties that are purported by the instant invention. In the absence of some understanding of the conditions to be treated one skilled in the art would not have concluded that Applicant was in possession of the claimed methods.

7. Claims 21, 22, 27-35, 37, 39-45, 50, 53, and 54 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed

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invention. The claims are drawn to a "method for inhibiting calcium channel activity in a cell having a calcium channel" as well as "a method of treating a subject having the disorder associated with calcium channel activity" by administering a compound of the general structural formula, as depicted in claim 27. The claimed methods of treatment fail to meet the requirement for an adequate written description of the claimed invention as required by 35 U.S.C. 112, first paragraph. There is insufficient descriptive support for the generic limitations a "method for inhibiting calcium channel activity in a cell having a calcium channel" as well as "a method of treating a subject having the disorder associated with calcium channel activity." This rejection is further supported by the fact that applicants have only adequately described the five (5) compounds that are encompassed by the family of compounds of the invention, as listed in Figures 2-6, as opposed to the litany of compounds that are embraced by the compounds of the general structural formulas of claims 21, 27, and 44. There is no description of an actual reduction to practice to show that the applicants were in possession of the claimed invention, especially in view of the fact that only five (5) compounds that are encompassed by the family of compounds of the invention, as listed in Figures 2-6, are adequately described in the instant specification.

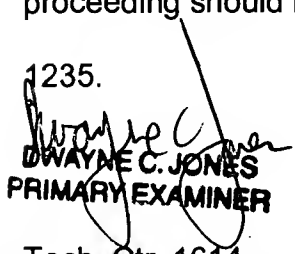
Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. C. Jones whose telephone number is (703) 308-4634. The examiner can normally be reached on Mondays through Fridays from 8:30 am to 6:00 pm. The examiner can also be reached on alternate Mondays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-

1235.


DWAYNE C. JONES
PRIMARY EXAMINER

Tech. Ctr. 1614
September 29, 2003